

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, and WISCONSIN, the DISTRICT OF COLUMBIA, the CITY OF CHICAGO, *ex rel.*, and OSWALD BILOTTA,

Plaintiffs,

-against-

NOVARTIS PHARMACEUTICALS  
CORPORATION,

Defendant.

**NOVARTIS PHARMACEUTICALS  
CORPORATION'S ANSWER TO  
THE COMPLAINT IN  
INTERVENTION OF THE  
STATE OF NEW YORK**

**11 CIV. 0071 (PGG)**

**JURY TRIAL REQUESTED**

For its Answer to the Complaint in Intervention of the State of New York ("Complaint"), dated August 26, 2013, Defendant Novartis Pharmaceuticals Corporation ("Novartis"), by its undersigned counsel, states as follows:<sup>1</sup>

**I. NATURE OF THE ACTION**

1. Admits the allegations in numbered paragraph 1 of the Complaint.
2. Denies the allegations in numbered paragraph 2 of the Complaint.
3. Denies the allegations in numbered paragraph 3 of the Complaint.

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<sup>1</sup> Each of the numbered paragraphs set forth herein responds to the corresponding paragraph in the Complaint. All headings used herein correspond to the headings set forth in the Complaint, and are used solely for purposes of convenience. To the extent that any of the headings in the Complaint assert allegations to which a response is deemed required, Novartis denies any such allegation. Any additional allegations in the Complaint that are not specifically admitted herein are denied.

4. Denies the allegations in numbered paragraph 4 of the Complaint.

5. Denies the allegations in numbered paragraph 5 of the Complaint, except admits that, in September 2010, Novartis entered into a settlement agreement with the United States Government, states and several relators to resolve civil claims regarding Novartis's promotion of certain drugs and signed a Corporate Integrity Agreement ("CIA") with the U.S. Department of Health and Human Services Office of Inspector General. Novartis respectfully refers the Court to the settlement agreement and the CIA for a full and complete reading of their content.

6. Denies the allegations in numbered paragraph 6 of the Complaint.

7. Denies the allegations in numbered paragraph 7 of the Complaint.

## **II. JURISDICTION AND VENUE**

8. Denies the allegations in numbered paragraph 8 of the Complaint, except admits that Eric T. Schneiderman is the Attorney General of the State of New York. To the extent numbered paragraph 8 of the Complaint states conclusions or characterizations of law, no response is required.

9. Admits the allegations in numbered paragraph 9 of the Complaint.

10. Admits the allegations in numbered paragraph 10 of the Complaint.

11. Because numbered paragraph 11 of the Complaint states conclusions or characterizations of law, no response is required.

12. Because numbered paragraph 12 of the Complaint states conclusions or characterizations of law, no response is required.

## **III. PARTIES**

13. Admits the allegations in numbered paragraph 13 of the Complaint.

14. Admits that Relator is a former employee of Novartis and denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations in numbered paragraph 14 of the Complaint.

15. Admits that Novartis is headquartered in East Hanover, New Jersey and markets and sells brand name prescription medications within the geographic boundaries over which the United States District Court for the Southern District of New York presides. Novartis further admits that Novartis is an indirect subsidiary of Novartis AG, a Swiss public company.

#### **IV. THE LAW**

16. Admits that the New York False Claims Act (“NY FCA”) contains the language quoted in numbered paragraph 16 of the Complaint and respectfully refers the Court to the Act for the full and complete reading of the text. To the extent that numbered paragraph 16 of the Complaint states conclusions or characterizations of law, no response is required.

17. Admits that the NY FCA contains the language quoted in numbered paragraph 17 of the Complaint and respectfully refers the Court to the Act for the full and complete reading of the text. To the extent that numbered paragraph 17 of the Complaint states conclusions or characterizations of law, no response is required.

18. Admits that the NY FCA contains the language quoted in numbered paragraph 18 of the Complaint and respectfully refers the Court to the Act for the full and complete reading of the text. To the extent that numbered paragraph 18 of the Complaint states conclusions or characterizations of law, no response is required.

19. Admits that N.Y. Social Services Law § 145-b(1)(a) contains the language quoted in numbered paragraph 19 of the Complaint and respectfully refers the Court to that provision for the full and complete reading of the text. To the extent that numbered paragraph 19 of the Complaint states conclusions or characterizations of law, no response is required.

20. Admits that N.Y. Social Services Law § 145-b(1)(b) contains the language quoted in numbered paragraph 20 of the Complaint and respectfully refers the Court to that provision for the full and complete reading of the text. To the extent that numbered paragraph 20 of the Complaint states conclusions or characterizations of law, no response is required.

21. Because numbered paragraph 21 of the Complaint states conclusions or characterizations of law, no response is required.

22. Admits that New York Executive Law § 63(12) contains the language quoted in numbered paragraph 22 of the Complaint and respectfully refers the Court to that provision for the full and complete reading of the text. To the extent that numbered paragraph 22 of the Complaint states conclusions or characterizations of law, no response is required.

23. Admits that New York Executive Law § 63-c(1) contains the language quoted in numbered paragraph 23 of the Complaint and respectfully refers the Court to that provision for the full and complete reading of the text. To the extent that numbered paragraph 23 of the Complaint states conclusions or characterizations of law, no response is required.

24. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 24 of the Complaint, except admits that Medicare is a federal program that provides coverage of some health care services for persons who are 65 or older or are disabled, and respectfully refers the Court to 42 U.S.C. §§ 1395 *et seq.* and related regulations for a description of the programs. To the extent that numbered paragraph 24 of the Complaint states conclusions or characterizations of law, no response is required.

25. Because numbered paragraph 25 of the Complaint states conclusions or characterizations of law, no response is required.

26. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 26 of the Complaint, except admits that 42 U.S.C.

§§ 1396b(a)(1) contains the language quoted in numbered paragraph 26 of the Complaint and respectfully refers the Court to that provision for the full and complete reading of the text. To the extent that numbered paragraph 26 of the Complaint states conclusions or characterizations of law, no response is required.

27. Because numbered paragraph 27 of the Complaint states conclusions or characterizations of law, no response is required.

28. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 28 of the Complaint. To the extent that numbered paragraph 28 of the Complaint states conclusions or characterizations of law, no response is required.

29. Admits that 18 N.Y.C.R.R. § 504.1 contains the language quoted in numbered paragraph 29 of the Complaint and respectfully refers the Court to that provision for the full and complete reading of the text. To the extent that numbered paragraph 29 of the Complaint states conclusions or characterizations of law, no response is required.

30. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 30 of the Complaint. To the extent that numbered paragraph 30 of the Complaint states conclusions or characterizations of law, no response is required.

31. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 31 of the Complaint. To the extent numbered paragraph 31 of the Complaint states conclusions or characterizations of law, no response is required.

32. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 32 of the Complaint. To the extent numbered paragraph 32 of the Complaint states conclusions or characterizations of law, no response is required.

33. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 33 of the Complaint. To the extent numbered paragraph 33 of the Complaint states conclusions or characterizations of law, no response is required.

34. Admits that 18 N.Y.C.R.R. § 515.2(b) contains the language quoted in numbered paragraph 34 of the Complaint and respectfully refers the Court to that provision for the full and complete reading of the text. To the extent that numbered paragraph 34 of the Complaint states conclusions or characterizations of law, no response is required.

35. Admits that 18 N.Y.C.R.R. § 515.2(a) contains the language quoted in numbered paragraph 35 of the Complaint and respectfully refers the Court to that provision for the full and complete reading of the text. To the extent that numbered paragraph 35 of the Complaint states conclusions or characterizations of law, no response is required.

36. Admits that 18 N.Y.C.R.R. § 518.1(c) contains the language quoted in numbered paragraph 36 of the Complaint and respectfully refers the Court to that provision for the full and complete reading of the text. To the extent that numbered paragraph 36 of the Complaint states conclusions or characterizations of law, no response is required.

37. Denies the allegations in numbered paragraph 37 of the Complaint, except admits that 18 N.Y.C.R.R. § 515.5(a), (b) contains the language quoted in numbered paragraph 37 of the Complaint and respectfully refers the Court to that provision for the full and complete reading of the text. To the extent that numbered paragraph 37 of the Complaint states conclusions or characterizations of law, no response is required.

38. Because numbered paragraph 38 of the Complaint states conclusions or characterizations of law, no response is required.

39. Admits that 42 U.S.C. § 1320a-7b(b) contains the language quoted in the second sentence of numbered paragraph 39 of the Complaint and respectfully refers the Court to the statute for the full and complete reading of the text. To the extent that numbered paragraph 39 of the Complaint states conclusions or characterizations of law, no response is required.

40. Because numbered paragraph 40 of the Complaint states conclusions or characterizations of law, no response is required.

41. Admits that 42 U.S.C. § 1320a-7b(g) contains the language quoted in numbered paragraph 41 of the Complaint and respectfully refers the Court to that provision for the full and complete reading of the text. To the extent that numbered paragraph 41 of the Complaint states conclusions or characterizations of law, no response is required.

42. Because numbered paragraph 42 of the Complaint states conclusions or characterizations of law, no response is required.

43. Because numbered paragraph 43 of the Complaint states conclusions or characterizations of law, no response is required.

44. Admits that the New York State Anti-Kickback Statute (“NY AKS”) contains the language quoted in numbered paragraph 44 of the Complaint and respectfully refers the Court to the statute for the full and complete reading of the text. To the extent that numbered paragraph 44 of the Complaint states conclusions or characterizations of law, no response is required.

45. Because numbered paragraph 45 of the Complaint states conclusions or characterizations of law, no response is required.

**V. FACTUAL ALLEGATIONS**

46. Denies the allegations in numbered paragraph 46 of the Complaint, except admits that Novartis had policies pertaining to compliance with the AKS and respectfully refers the Court to the policies for a full and complete reading of their content.

47. Denies the allegations in numbered paragraph 47 of the Complaint, except admits that Novartis had policies pertaining to compliance with the AKS and respectfully refers the Court to the policies for a full and complete reading of their content.

48. Denies the allegations in numbered paragraph 48 of the Complaint, except admits that Novartis complies with the AKS when promoting medicines to health care professionals and has had policies pertaining to compliance with the AKS and respectfully refers the Court to the policies for a full and complete reading of their content.

49. Denies the allegations in numbered paragraph 49 of the Complaint, except admits that Novartis is a member of the Pharmaceutical Research and Manufacturers of America (“PhRMA”) and a signatory of the PhRMA Code and further respectfully refers the Court to the PhRMA Code for a full and complete reading of its content.

50. Denies the allegations in numbered paragraph 50 of the Complaint, except admits that Novartis had policies pertaining to physician speaker programs and respectfully refers the Court to the policies for a full and complete reading of their content.

51. Denies the allegations in numbered paragraph 51 of the Complaint, except admits the existence of a PhRMA Code and refers to that document for its content.

52. Denies the allegations in numbered paragraph 52 of the Complaint, except admits the existence of a PhRMA Code and refers to that document for its content.

53. Denies the allegations in numbered paragraph 53 of the Complaint, except admits that Novartis had policies pertaining to physician speaker programs, including that speaker



programs have legitimate purposes, and respectfully refers the Court to the policies for a full and complete reading of their content.

54. Admits that, in September 2010, Novartis entered into a settlement agreement with the U.S. Government, states and several relators to resolve civil claims and further admits that the language quoted in numbered paragraph 54 of the Complaint is contained in the settlement agreement and respectfully refers to Court to the settlement agreement for a full and complete reading of its content.

55. Admits that, in September 2010, Novartis entered into a CIA with the Office of Inspector General of the Department of Health and Human Services and further admits that the language quoted in numbered paragraph 55 of the Complaint is contained in the CIA and respectfully refers to Court to the CIA for a full and complete reading of its content.

56. Admits that the language quoted in numbered paragraph 56 of the Complaint is contained in the CIA and respectfully refers to Court to the CIA for a full and complete reading of its content.

57. Denies the allegations in numbered paragraph 57 of the Complaint, except admits that Novartis promoted, as part of its cardiovascular portfolio:

- Lotrel from 1995 - 2008
- Diovan from 1997 - present
- Diovan HCT from 1998 - present
- Tekturna from 2007 - present
- Exforge from 2007 - present
- Tekturna HCT from 2008 - present
- Exforge HCT from 2009 - present

- Valturna from 2009 - 2011
- Tekamlo from 2010 - present.

58. Denies the allegations in numbered paragraph 58 of the Complaint, except admits that NPC sold the drugs identified in paragraph 57, above.

59. Admits the allegations in numbered paragraph 59.

60. Admits the allegations in the first and second sentences of numbered paragraph 60 of the Complaint but states that Starlix was approved by the FDA in December 2000. Denies the allegations in the third sentence of numbered paragraph 60 of the Complaint. Admits Valturna is a combination of aliskiren and valsartan and Diovan HCT is a combination of valsartan and hydrochlorothiazide.

61. Denies the allegations in numbered paragraph 61 of the Complaint.

62. Denies the allegations in numbered paragraph 62 of the Complaint.

63. Denies the allegations in numbered paragraph 63 of the Complaint.

64. Denies the allegations in numbered paragraph 64 of the Complaint.

65. Denies the allegations in numbered paragraph 65 of the Complaint.

66. Denies the allegations in numbered paragraph 66 of the Complaint, except admits that Novartis had policies regarding the compensation of speakers who conducted speaker programs and respectfully refers the Court to those policies for a full and complete reading of their content.

67. Denies the allegations in numbered paragraph 67 of the Complaint.

68. Denies the allegations in numbered paragraph 68 of the Complaint, except admits that Novartis had policies regarding the compensation of persons being trained to conduct

speaker programs and respectfully refers the Court to those policies for a full and complete reading of their content.

69. Denies the allegations in numbered paragraph 69 of the Complaint.

70. Denies the allegations in numbered paragraph 70 of the Complaint, except admits that since 2007, Advanced Health Media has maintained a database related to NPC speaker programs, among other things.

71. Denies the allegations in numbered paragraph 71 of the Complaint.

72. Denies the allegations in numbered paragraph 72 of the Complaint, except admits that Novartis had policies pertaining to physician speaker programs and respectfully refers the Court to the policies for a full and complete reading of their content.

73. Denies the allegations in numbered paragraph 73 of the Complaint.

74. Denies the allegations in numbered paragraph 74 of the Complaint, except admits that Novartis had policies pertaining to physician speaker programs and respectfully refers the Court to the policies for a full and complete reading of their content.

75. Denies the allegations in numbered paragraph 75 of the Complaint.

76. Denies the allegations in numbered paragraph 76 of the Complaint.

77. Denies the allegations in numbered paragraph 77 of the Complaint.

78. Denies the allegations in numbered paragraph 78 of the Complaint.

79. Denies the allegations in numbered paragraph 79 of the Complaint.

80. Denies the allegations in numbered paragraph 80 of the Complaint, except admits that managers of sales representatives as part of their jobs supervised the activity of sales representatives regarding speaker programs.

81. Denies the allegations in numbered paragraph 81 of the Complaint.

82. Denies the allegations in numbered paragraph 82 of the Complaint.
83. Denies the allegations in numbered paragraph 83 of the Complaint.
84. Denies the allegations in numbered paragraph 84 of the Complaint.
85. Denies the allegations in numbered paragraph 85 of the Complaint.
86. Denies the allegations in numbered paragraph 86 of the Complaint.
87. Denies the allegations in numbered paragraph 87 of the Complaint.
88. Denies the allegations in numbered paragraph 88 of the Complaint.
89. Denies the allegations in numbered paragraph 89 of the Complaint.
90. Denies the allegations in numbered paragraph 90 of the Complaint.
91. Denies the allegations in numbered paragraph 91 of the Complaint.
92. Denies the allegations in numbered paragraph 92 of the Complaint.
93. Denies the allegations in numbered paragraph 93 of the Complaint.
94. Denies the allegations in numbered paragraph 94 of the Complaint.
95. Denies the allegations in numbered paragraph 95 of the Complaint.
96. Denies the allegations in numbered paragraph 96 of the Complaint.
97. Denies the allegations in numbered paragraph 97 of the Complaint. To the extent numbered paragraph 97 of the Complaint states conclusions or characterizations of law, no response is required.
98. Denies the allegations in numbered paragraph 98 of the Complaint.
99. Denies the allegations in numbered paragraph 99 of the Complaint.
100. Denies the allegations in numbered paragraph 100 of the Complaint.
101. Denies the allegations in numbered paragraph 101 of the Complaint.
102. Denies the allegations in numbered paragraph 102 of the Complaint.

103. Denies the allegations in numbered paragraph 103 of the Complaint.

104. Denies the allegations in numbered paragraph 104 of the Complaint.

105. Denies the allegations in numbered paragraph 105 of the Complaint.

106. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 106 of the Complaint.

107. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 107 of the Complaint.

108. Denies the allegations in numbered paragraph 108 of the Complaint.

109. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 109 of the Complaint.

110. Denies the allegations in numbered paragraph 110 of the Complaint.

111. Denies the allegations in numbered paragraph 111 of the Complaint.

112. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 112 of the Complaint.

113. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 113 of the Complaint.

114. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 114 of the Complaint.

115. Denies the allegations in numbered paragraph 115 of the Complaint.

116. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 116 of the Complaint.

117. Denies the allegations in numbered paragraph 117 of the Complaint.

118. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 118 of the Complaint.

119. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 119 of the Complaint.

120. Denies the allegations in numbered paragraph 120 of the Complaint.

121. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 121 of the Complaint.

122. Denies the allegations in numbered paragraph 122 of the Complaint.

123. Denies the allegations in numbered paragraph 123 of the Complaint.

124. Denies the allegations in numbered paragraph 124 of the Complaint.

125. Denies the allegations in numbered paragraph 125 of the Complaint.

126. Denies the allegations in numbered paragraph 126 of the Complaint.

127. Denies the allegations in numbered paragraph 127 of the Complaint.

128. Denies the allegations in numbered paragraph 128 of the Complaint.

129. Denies the allegations in numbered paragraph 129 of the Complaint, except admits that the referenced presentation titled “Representatives [sic] Interactions with Healthcare Professionals” contains the language quoted in numbered paragraph 129 and respectfully refers the Court to presentation for a full and complete reading of its content.

130. Denies the allegations in numbered paragraph 130 of the Complaint.

131. Denies the allegations in numbered paragraph 131 of the Complaint.

132. Denies the allegations in numbered paragraph 132 of the Complaint and refers the Court to the March 9, 2011 report for a full and complete reading of its content.

133. Denies the allegations in numbered paragraph 133 of the Complaint, except admits that Novartis promoted Diovan, Diovan HCT, Tekturna, Tekturna HCT, Tekamlo, Exforge, and Exforge HCT as set forth in paragraph 57, above. To the extent that numbered paragraph 133 of the Complaint states conclusions or characterizations of law, no response is required.

134. Denies the allegations in numbered paragraph 134 of the Complaint, except admits that Novartis promoted Diovan, Tekturna and Exforge as set forth in paragraph 57, above.

135. Denies the allegations in numbered paragraph 135 of the Complaint. To the extent numbered paragraph 135 of the Complaint states conclusions or characterizations of law, no response is required.

136. Denies the allegations in numbered paragraph 136 of the Complaint. To the extent numbered paragraph 136 of the Complaint states conclusions or characterizations of law, no response is required.

137. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 137 of the Complaint. To the extent that numbered paragraph 137 of the Complaint states conclusions or characterizations of law, no response is required.

138. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 138 of the Complaint. To the extent that numbered paragraph 138 of the Complaint states conclusions or characterizations of law, no response is required.

139. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 139 of the Complaint.

140. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in numbered paragraph 140 of the Complaint.

141. Denies the allegations in numbered paragraph 141 of the Complaint. To the extent that numbered paragraph 141 of the Complaint states conclusions or characterizations of law, no response is required.

142. Denies the allegations in numbered paragraph 142 of the Complaint. To the extent that numbered paragraph 142 of the Complaint states conclusions or characterizations of law, no response is required.

143. Denies the allegations in numbered paragraph 143 of the Complaint. To the extent that numbered paragraph 143 of the Complaint states conclusions or characterizations of law, no response is required.

144. Denies the allegations in numbered paragraph 144 of the Complaint. To the extent that numbered paragraph 144 of the Complaint states conclusions or characterizations of law, no response is required.

145. Denies the allegations in numbered paragraph 145 of the Complaint. To the extent that numbered paragraph 145 of the Complaint states conclusions or characterizations of law, no response is required.

146. Denies the allegations in numbered paragraph 146 of the Complaint. To the extent that numbered paragraph 146 of the Complaint states conclusions or characterizations of law, no response is required.

147. Denies the allegations in numbered paragraph 147 of the Complaint. To the extent that numbered paragraph 147 of the Complaint states conclusions or characterizations of law, no response is required.



**FIRST CLAIM FOR RELIEF**

148. Novartis repeats and incorporates herein the responses to numbered paragraphs 1 through 147 of the Complaint above.

149. Denies the allegations in numbered paragraph 149 of the Complaint. To the extent that numbered paragraph 149 of the Complaint states conclusions or characterizations of law, no response is required.

150. Denies the allegations in numbered paragraph 150 of the Complaint. To the extent that numbered paragraph 150 of the Complaint states conclusions or characterizations of law, no response is required.

**SECOND CLAIM FOR RELIEF**

151. Novartis repeats and incorporates herein the responses to numbered paragraphs 1 through 150 of the Complaint above.

152. Denies the allegations in numbered paragraph 152 of the Complaint. To the extent that numbered paragraph 152 of the Complaint states conclusions or characterizations of law, no response is required.

153. Denies the allegations in numbered paragraph 153 of the Complaint. To the extent that numbered paragraph 153 of the Complaint states conclusions or characterizations of law, no response is required.

**THIRD CLAIM FOR RELIEF**

154. Novartis repeats and incorporates herein the responses to numbered paragraphs 1 through 153 of the Complaint above.

155. Denies the allegations in numbered paragraph 155 of the Complaint. To the extent that numbered paragraph 155 of the Complaint states conclusions or characterizations of law, no response is required.

156. Denies the allegations in numbered paragraph 156 of the Complaint. To the extent that numbered paragraph 156 of the Complaint states conclusions or characterizations of law, no response is required.

157. Denies the allegations in numbered paragraph 157 of the Complaint. To the extent that numbered paragraph 157 of the Complaint states conclusions or characterizations of law, no response is required.

158. Denies the allegations in numbered paragraph 158 of the Complaint. To the extent that numbered paragraph 158 of the Complaint states conclusions or characterizations of law, no response is required.

#### **FOURTH CLAIM FOR RELIEF**

159. Novartis repeats and incorporates herein the responses to numbered paragraphs 1 through 158 of the Complaint above.

160. Admits that N.Y. Executive Law § 63(12) contains the language quoted in numbered paragraph 160 and respectfully refers the Court to that provision for a full and complete reading of its content. To the extent that numbered paragraph 160 of the Complaint states conclusions or characterizations of law, no response is required.

161. Denies the allegations in numbered paragraph 161 of the Complaint. To the extent that numbered paragraph 161 of the Complaint states conclusions or characterizations of law, no response is required.

162. Denies the allegations in numbered paragraph 162 of the Complaint. To the extent that numbered paragraph 162 of the Complaint states conclusions or characterizations of law, no response is required.

**FIFTH CLAIM FOR RELIEF**

163. Novartis repeats and incorporates herein the responses to numbered paragraphs 1 through 162 of the Complaint above.

164. Denies the allegations in numbered paragraph 164 of the Complaint.

**SIXTH CLAIM FOR RELIEF**

165. Novartis repeats and incorporates herein the responses to numbered paragraphs 1 through 164 of the Complaint above.

166. Denies the allegations in numbered paragraph 166 of the Complaint.

167. Denies the allegations in numbered paragraph 167 of the Complaint.

**AFFIRMATIVE DEFENSES**

By alleging the matters set forth below, Novartis does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters or that the State is relieved of its burden to prove each and every element of its claims and the damages, if any, to which it is entitled. Novartis reserves the right to raise any additional defenses, cross-claims and third party claims not asserted herein of which it may become aware through discovery or other investigation.

**FIRST AFFIRMATIVE DEFENSE**

The State fails to state a claim against Novartis upon which relief may be granted, and the Complaint should be dismissed.

**SECOND AFFIRMATIVE DEFENSE**

The State fails to allege any false claim under the New York False Claims Act because Novartis's conduct did not result in any "false or fraudulent claim" in violation the New York State False Claims Act, N.Y. State Finance Law §§ 187-190.

**THIRD AFFIRMATIVE DEFENSE**

The State fails to allege that any claim submitted prior to March 2010 was a false or fraudulent claim under the New York False Claims Act because those claims did not contain or otherwise incorporate express or implied statements that were false or fraudulent as a result of the conduct alleged against Novartis.

**FOURTH AFFIRMATIVE DEFENSE**

The State's claims fail because Novartis's alleged conduct did not involve any "illegal remuneration" in violation of New York False Claims Act.

**FIFTH AFFIRMATIVE DEFENSE**

The State's claims are barred, in whole or in part, because Novartis's alleged conduct falls within applicable statutory or regulatory exceptions or "safe harbors" in the Anti-Kickback Statute and any state law counterparts.

**SIXTH AFFIRMATIVE DEFENSE**

The State's claims fail because, at all times relevant hereto, Novartis complied with all applicable federal and state regulations.

**SEVENTH AFFIRMATIVE DEFENSE**

The State's claims are released, estopped and/or barred, in whole or in part, by the September 2010 settlement agreement between the Department of Justice and Novartis.

**EIGHTH AFFIRMATIVE DEFENSE**

The State's claims are barred, in whole or in part, because they rely upon ambiguous provisions of the New York False Claims Act and other provisions of law, and the rule of lenity requires such ambiguities to be construed in Novartis's favor.

**NINTH AFFIRMATIVE DEFENSE**

The State's claims are barred, in whole or in part, because they violate Novartis's rights under the Due Process and Ex Post Facto clauses of the United States Constitution and the

New York State Constitution, insofar as the State seeks to impose liability retroactively for conduct that is not prohibited by federal and state statutes or regulations.

**TENTH AFFIRMATIVE DEFENSE**

The State's claims fail because any and all actions taken by Novartis with respect to any of the matters alleged in the Complaint were taken in accordance with established industry practice.

**ELEVENTH AFFIRMATIVE DEFENSE**

The State's claims are barred, in whole or in part, by the applicable statutes of limitations and repose.

**TWELFTH AFFIRMATIVE DEFENSE**

The State's claims are barred, in whole or in part, by the doctrine of consent and/or ratification.

**THIRTEENTH AFFIRMATIVE DEFENSE**

The State's claims are barred, in whole or in part, by the doctrines of laches, estoppel and waiver.

**FOURTEENTH AFFIRMATIVE DEFENSE**

The State's claims for damages are barred or should be reduced based on the State's failure to mitigate damages.

**FIFTEENTH AFFIRMATIVE DEFENSE**

The State's claims fail because, to the extent that the State attempts to seek equitable relief against Novartis, the State has an adequate remedy at law.

**SIXTEENTH AFFIRMATIVE DEFENSE**

The State's claims fail because, to the extent civil penalties are sought against Novartis, such civil penalties would violate the Excessive Fines Clause of the Eighth

Amendment and the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution and corresponding clauses under the New York State Constitution.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

The State's claims fail because, to the extent that the State is alleging fraud or similar conduct, it has failed to plead fraud with particularity.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

The State's claims fail because they are too remote and speculative to form the basis for relief.

**NINETEENTH AFFIRMATIVE DEFENSE**

The State's claims fail because it has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Novartis as alleged in the Complaint.

**TWENTIETH AFFIRMATIVE DEFENSE**

The State's claims are barred, in whole or in part, because the State's injuries were not proximately caused by the acts or omissions of Novartis but, if they exist at all, were the result in whole or in part of intervening or supervening causes.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

To the extent the State obtains or obtained recovery in any other proceeding predicated on the same factual allegations, the State is barred from seeking recovery against Novartis based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

The State's claims are barred, in whole or in part, to the extent that they seek to impose upon Novartis obligations that are inconsistent with, or in excess of, those imposed by existing law.

**Prayer for Relief**

Wherefore Defendant Novartis Pharmaceuticals Corporation respectfully prays as follows:

1. That the State's Complaint against Novartis be dismissed with prejudice in its entirety; and
2. For such other and further relief as this Court deems just and proper, including, but not limited to, costs, disbursements and reasonable attorneys' fees incurred by Novartis in defending this action, plus interest on any sums awarded thereunder.

Dated: October 14, 2014

/s/ Rachel G. Skaistis  
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Rachel G. Skaistis  
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Novartis Pharmaceuticals Corporation*